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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/534,486

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Takanori Matsuo

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08/12/2009

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EXAMINER

EWOLDT, GERALD R

ART UNIT

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1644

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/534,486	<b>Applicant(s)</b> MATSUO ET AL.	
	<b>Examiner</b> G. R. Ewoldt, Ph.D.	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2009 and 03 June 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-12, 15, 17-31, 34, 35 and 38-43 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-12, 19-31, 34 and 35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 15, 17, 18 and 38-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/09</u> .   | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed 6/03/09 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's IDS filed 2/17/09 and amendment, remarks, and IDS filed 6/03/09 have been entered.

2. Claims 1-8, 10-12, 19-31, 34, and 35 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected inventions.

Claims 9, 15, 17, and 18, and 38-43 are under examination.

3. In view of Applicant's amendment and remarks, and upon reconsideration all previous rejections have been withdrawn. Where appropriate the remarks concerning the previous rejection under 35 U.S.C. 103(a) will be addressed.

4. Claims 9, 15, 17, and 18, and 38-43 are objected to. First, all claims must consist of a single sentence, e.g., We claim: ...a screening method for... As are currently pending the instant claims consist only of sentence fragments. Additionally, each method step, e.g., those of Claim 1, must be indented, see MPEP 608.01(m).

5. The following are new grounds for rejection.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 9, 15, 17, and 18, and 38-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,617,440 in view of Ihara et al. (2001, of record) and

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Flyvbjerg et al. (2002).

The '440 patent teaches a screening method for a therapeutic substance (a compound which exhibits the ability to promote muscle growth) (see particularly column 8, lines 35-40) comprising cultivating a cell (the administered cell had to have been "cultivated") and comparing the expression of a gene in the presence or absence of a test compound. Said method further includes the assaying of mRNA expression (see particularly column 7, line 63 - column 8, line 13).

The reference differs from the claimed invention in that it does not teach comparing the expression of a gene encoding the protein of SEQ ID NO:2.

Ihara et al. teaches the protein of SEQ ID NO:2 (TSC-22), is associated with diabetes. In particular, the expression of the gene of SEQ ID NO:1 can be used as a marker for insulin expression. TSC-22 inhibits insulin expression such that a measure of TSC-22 expression can be used as a measure of insulin expression and the reduction of TSC-22 expression is an indication of increased insulin expression (see the entire Abstract).

Flyvbjerg et al. teaches that diabetic nephropathy in type 2 diabetic patients is a frequent complication; indeed, it is the most common cause of end stage renal failure in the Western world (see particularly page 3090, column 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to employ the screening method of the '440 patent employing the measuring of the expression of the TSC-22 gene of Ihara et al. given the relationship of TSC-22 expression and insulin expression. Said method could be used as a method for screening test substances for their effect on TSC-22 expression as a measure of their efficacy as a therapeutic for the treatment of diabetes. Further, Flyvbjerg et al. teach that diabetic nephropathy in type 2 diabetic patients is a frequent complication; indeed, it is the most common cause of end stage renal failure in the Western world thus, treatments for diabetes would comprise needed treatments for one of the most common renal diseases.

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Applicant's arguments, filed 6/03/09, have been fully considered but are not found persuasive. Applicant's arguments regarding the mechanism of the reporter gene operation and the claim limitations requiring the measurement of mRNA expression have been addressed in the new rejection.

Applicant raises one argument that will be further addressed here, i.e., that the model of Ihara et al. is not an appropriate model for diabetic nephropathy.

Flyvbjerg et al. teaches that diabetic nephropathy in type 2 diabetic patients is a frequent severe complication. Thus, regardless of animal models employed, treatments for diabetes would be expected to reduce this complication in humans, i.e., simply treating the disease would reduce any complications of the disease. Accordingly, finding new treatments for diabetes would comprise an obvious way to find new treatments for renal disease of which diabetic nephropathy is the major one.

8. No claim is allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0841.

10. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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